

Amendments to the Claims:

This listing of claims will replace all prior versions, and listings, of claims in the application.

Listing of Claims:

Claim 1 (currently amended): A method of sterilizing a medical device component having an inner chamber or lumen, comprising applying an electron beam to the component in an evacuated or inert gas-filled container, wherein air present in the inner chamber or lumen after formation of the medical device component is purged before ~~being~~ the medical device component is placed in the container by evacuating ~~the medical device component~~ and filling the medical device component inner chamber or lumen with an inert gas.

Claim 2 (original): The method of claim 1 including sealing the container so that the container is airtight, after the medical device component is placed therein and before the electron beam is applied.

Claim 3 (original): The method of claim 2 including purging the container by evacuating the container and filling the evacuated container with inert gas, before the container is sealed.

Claim 4 (cancelled)

Claim 5 (previously presented): The method of claim 3 wherein the medical device component is selected from the group consisting of a catheter shaft and a catheter balloon, and the medical device component is purged before the container is filled with the inert gas.

Claim 6 (cancelled)

Claim 7 (original): The method of claim 5 wherein the medical device component and the container are purged inside an evacuated or inert gas-filled chamber.

Claim 8 (original): The method of claim 7 wherein the container is sealed inside the chamber.

Claim 9 (original): The method of claim 1 wherein the electron beam has an energy of about 3 to about 10 MRads.

Claim 10 (original): The method of claim 9 wherein the electron beam is applied in a single dose of about 2 to about 10 seconds.

Claim 11 (original): The method of claim 1 wherein the electron beam is applied in multiple doses, each dose being about 2 to about 10 seconds at an electron beam energy of about 2 to about 5 MRads.

Claim 12 (original): The method of claim 1 wherein the medical device component is formed of a polymeric material selected from the group consisting of a fluoropolymer, polytetrafluoroethylene, expanded polytetrafluoroethylene, and polyether block amide, and including applying the electron beam at an energy level of about 2 to about 10 MRads.

Claim 13 (cancelled)

Claim 14 (previously presented): A method of sterilizing a balloon of a balloon catheter, comprising

- a) providing a balloon catheter having a balloon with a first rupture pressure;
- and
- b) applying an electron beam to the balloon catheter in an evacuated or inert gas-filled container, so that the electron-beamed balloon has a second rupture pressure equal to or less than the first rupture pressure, the second rupture pressure being not more than about 15% to about 25% less than the first rupture pressure.

Claim 15 (original): The method of claim 14 including purging the container with the balloon catheter therein by evacuating the container and filling the evacuated container with inert gas, and sealing the purged container with the balloon catheter therein, before the electron beam is applied.

Claim 16 (original): The method of claim 15 including purging the balloon catheter by evacuating the balloon catheter and filling with inert gas, before the container sealed.

Claim 17 (original): The method of claim 16 wherein the balloon catheter is purged before being placed in the container and before the container is purged.

Claim 18 (original): The method of claim 16 wherein the container is purged inside an evacuated or inert gas-filled chamber.

Claim 19 (original): The method of claim 16 wherein the purged container is sealed inside the evacuated or inert gas-filled chamber.

Claim 20 (original): The method of claim 15 including mounting a stent on an outer surface of the balloon before the electron beam is applied, and the electron beam is applied to the outer surface of the balloon so that the stent reduces penetration of the electron beam into sections of the balloon located directly underneath the stent.

Claim 21 (currently amended): A method of sterilizing a balloon catheter having a balloon on an elongated shaft, comprising

a) purging the balloon catheter by evacuating the balloon catheter and filling the evacuated balloon catheter with an inert gas, and purging a container, with the purged balloon catheter in the container, by evacuating the container and filling the evacuated container with an inert gas, and sealing the purged container to form an air tight, inert gas-filled container, and

b) applying an electron beam to the purged balloon catheter in the air tight, inert gas-filled container, to sterilize the balloon catheter, such that the balloon has a first fatigue resistance before the sterilization and a second fatigue resistance after the sterilization, and the electron beam is applied to the purged balloon catheter such that the second fatigue resistance is not more than about 5% to about 10% less than the first fatigue resistance.

Claim 22 (original): The method of claim 21 wherein the balloon has a first rupture pressure before the sterilization and a second rupture pressure after the sterilization, and the electron beam is applied to the purged balloon catheter such that the second rupture pressure of the balloon is not more than about 10% to about 15% less than the first rupture pressure.

Claims 23-26 (cancelled)

Claim 27 (previously presented): A balloon catheter, comprising an elongated shaft and a balloon mounted on the shaft, sterilized by an electron beam applied to the

balloon catheter in an evacuated or inert gas-filled container, so that the balloon has a first rupture pressure before the sterilization, and a second rupture pressure after the sterilization which is equal to or less than the first rupture pressure of the balloon and which is not significantly less than the first rupture pressure of the balloon, the second rupture pressure being not more than about 15% to about 25% less than the first rupture pressure.

Claim 28 (original): The balloon catheter of claim 27 wherein the second rupture pressure of the balloon is at least about 15 to about 20 atm.

Claim 29 (original): The balloon catheter of claim 27 wherein the balloon has a first fatigue resistance before the sterilization and a second fatigue resistance after the sterilization which is not more than about 5% to about 10% less than the first fatigue resistance of the balloon.

Claim 30 (original): The balloon catheter of claim 27 wherein the balloon has a wall thickness of about 0.01 to about 0.03 mm.

Claim 31 (original): The balloon catheter of claim 27 wherein the balloon is formed of a polyether block amide polymeric material.

Claim 32 (previously presented): A stent delivery balloon catheter, comprising an elongated shaft, and balloon mounted on the shaft and formed of a polyether block amide, and a stent mounted on the balloon for implanting in a patient's body lumen, the balloon being sterilized by an electron beam applied to the balloon catheter in an evacuated or inert gas-filled container with the stent mounted on the balloon so that sections of the balloon located directly underneath the stent are penetrated less by the electron beam than are sections of the balloon located at spaces in a wall of the stent, the balloon having a first rupture pressure before the electron beam sterilization, and a second rupture pressure after the electron beam sterilization which is equal to or less than the first rupture pressure of the balloon and which is not more than about 5% to about 25% less than the first rupture pressure of the balloon.

Claim 33 (currently amended): A method of sterilizing a balloon catheter, comprising:

- a) mounting a metallic stent on an outer surface of a balloon of the balloon catheter and purging air present within an interior of the balloon catheter after formation of the balloon catheter;
- b) purging a container with the purged balloon catheter therein by evacuating the container and filling the evacuated container with inert gas, and sealing the purged container with the purged balloon catheter therein; and
- c) applying an electron beam to the balloon catheter in the purged container, so that the electron beam is applied to the outer surface of the balloon so that

the electron beam penetration into sections of the balloon located directly underneath the stent is reduced by the metal of the metallic stent.

Claim 34 (previously presented): The method of claim 33 wherein the electron beam is applied to the balloon catheter without formation of reactive radicals.

Claim 35 (previously presented): The stent delivery balloon catheter of claim 32 wherein the stent is a metallic stent.

Claim 36 (previously presented): The balloon catheter of claim 27 wherein the balloon is formed of a polymeric material selected from the group consisting of a fluoropolymer, polytetrafluoroethylene, expanded polytetrafluoroethylene, and polyether block amide, and the electron beam is applied to the balloon catheter in an evacuated and/or an inert gas-filled condition.

Claim 37 (previously presented): The balloon catheter of claim 27 wherein the balloon is formed of a polymeric material selected from the group consisting of polyamides and fluoropolymers, and including a stent mounted on the balloon for implanting in a patient's body lumen.



Claim 38 (new): A balloon catheter, comprising an elongated shaft and a balloon mounted on the shaft, sterilized by an electron beam applied to the balloon catheter in an evacuated or inert gas-filled environment, so that the balloon has a first rupture pressure before the sterilization, and a second rupture pressure after the sterilization which is equal to or less than the first rupture pressure of the balloon and which is not significantly less than the first rupture pressure of the balloon, the second rupture pressure being not more than about 15% to about 25% less than the first rupture pressure